UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 1085-13
Program	Prior Authorization/Notification
Medication	Ravicti™ (glycerol phenylbutyrate oral liquid)
P&T Approval Date	04/2013, 4/2014, 4/2015, 2/2016, 12/2016, 12/2017, 12/2018, 2/2019, 2/2020, 2/2021, 2/2022
Effective Date	5/1/2022; Oxford only: N/A

1. Background

Ravicti (glycerol phenylbutyrate) is a nitrogen-binding agent indicated for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

Ravicti is not indicated for treatment of acute hyperammonemia in patients with UCDs. The safety and efficacy for treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established. [1]

Coverage for Ravicti will be provided for patients who meet the following criteria:

2. Coverage Criteria:

A. Initial Authorization

1. **Ravicti** will be approved based on **all** of the following criteria:

   a. Diagnosis of urea cycle disorders (UCDs)

   -AND-

   b. Inadequate response to **one** of the following:

      (1) Dietary protein restriction
      (2) Amino acid supplementation

   -AND-

   c. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Ravicti** will be approved based on **<u>both</u>** of the following criteria:

   a. Documentation of positive clinical response to Ravicti therapy

   -AND-

   b. Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Medical Necessity and/or Step Therapy may be in place.

4. References:

1. Ravicti® [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; September 2021.

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Change Control	
4/2014	Annual review with no change to clinical coverage. Updated reference.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
4/2015	Annual review with no change to clinical coverage. Updated background and reference.
2/2016	Annual review with no change to clinical coverage. Updated reference.
12/2016	Annual review. Updated background, formatting and reference.
12/2017	Annual review with no change to clinical coverage. Updated background and reference.
12/2018	Administrative change to add statement regarding use of automated processes.
12/2018	Annual review. No changes to clinical coverage criteria.
2/2019	Updated background and criteria to align with updated indication allowing use in patients less than 2 months of age.

2/2020	Annual review with no change to clinical coverage. Updated reference.
2/2021	Annual review with no change to clinical coverage.
2/2022	Annual review with no change to clinical coverage. Updated reference.